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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,256	06/08/2001	Susan D. Wilson	469201-651	8180

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EXAMINER
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SALIMI, ALI REZA

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 05/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/876,256

Applicant(s)

WILSON ET AL

Examiner

A R Salimi

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 7-44 and 46-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/20/01.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1648

### **DETAILED ACTION**

Claims 1-54 are pending.

Raw Sequence Listing have been entered.

Submitted Information Disclosure Statement (I.D.S) is noted.

#### ***Election/Restrictions***

Applicant's election with traverse of Group I (claims 1-6, and 45) in Paper filed 4/26/2004 is acknowledged. However, since the applicant set no argument forth the election was treated as an Election **without** traverse. Hence, claims 7-44, 46-54 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected Groups. Claims 1-6, and 45 are considered.

**Applicants are reminded to cancel the claims to the non-elected claims.**

#### ***Specification***

The disclosure is objected to because of the following informalities: the application contains sequence disclosures that are encompassed by the definitions, to fully comply the disclosure should be amended appropriately, and specific identification number should identify the sequences. For example, see specification page 9, Table 1, page 26.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

Claims 1-6, and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite for recitation of “chimeric HPV L1” which requires two HPV L1 fused together, however, none of the intended L1 proteins are defined. The claim is also confusing for recitation of “capable of”, this limitation does not set forth positively whether or not the chimeric protein actually does induce cellular response or not. In addition, the claim is vague for recitation of “generally comparable”, what does this mean, how does this generalization determined. The claim has been interpreted in light of the specification and since there is no teaching for such “general comparison”, the claim is vague and indefinite. This affects the dependent claims.

Claim 3 is vague and indefinite the intended “R5” epitope is/are not defined, what applicant’s regard as “R5 epitope” could be different from what others would consider to be R5. Identify the epitope by a specific sequence. This affects the dependent claims.

Claim 45 is vague and indefinite the intended L1 chimeric proteins are not defined.

***Claim Rejections - 35 USC § 112***

Claims 1-6, and 45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for chimeric L1 of HPV-18/HPV-45 inducing humoral response and method of inducing humoral response, does not reasonably provide enablement for therapeutic infection of human papillomavirus and induction of cellular response, and/or general

Art Unit: 1648

composition where a chimeric protein would induce a response that are generally comparable to those induced by two or more individual HPV types. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. First, the specification does not provide any comparison data where a general chimera protein would generate humoral response for two or more unrelated HPV types. Applicants have formed a chimera between two highly identical L1 proteins namely HPV-18, and HPV-45 and have observed high serum antibody as compare to a single administration of either HPV-18, or HPV-45 L1 protein. However, there is nothing in the specification that teaches whether or not chimera HPV18/HPV-45 did even induce antibody against for instance HPV-16. The scope of broad claims leads one to believe that any chimera would induce positive response against any and all types of papillomavirus. This is clearly not taught and it would be undue experimentation to fully enable the claimed invention.

Second, the specification is deficient in providing adequate teaching for induction of therapeutic and cellular response for treatment of papillomavirus infection. The disclosure teaches a method and composition for induction of antibody or humoral response, which is vastly different than cellular response which would require induction of TH1 type response wherein cascade of macrophages, dendritic, and/or T cells are suppose to be induced. The specification teaches induction of antibodies, there is no teaching that an existing infection of papillomavirus can be treated with the applicants' chimera or method of using the chimera. The disclosure provides no teaching that any MHC response has been observed. The state of the art is highly unpredictable for treatment of papillomavirus infection, as evidence see post-filing teaching by

Art Unit: 1648

Steller M. A. (Current Opinion in Investigational Drugs, 2002, Vol. 3, No. 1, pages 37-47) where it is indicated that virus like particles based vaccine would not confer protection for infected patient (see page 39, left column 3<sup>rd</sup> paragraph). If the state of post filing is not enabling for treating papillomavirus infection, hence, it is determined that applicants at the time of filing did not provide adequate teaching within the broad scope of the claimed invention. Hence, It is deemed to enable the full scope of the claimed invention one of ordinary skill in the art would be required large quantity of experimentations. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands*, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Gissmann et al (WO 99/18220).

The teaching and the claims of the above cited reference meets the broad limitations of the claims. The above cited art taught various chimeric virus like particles as now claimed (see claims 2-4). In addition, the above art also taught a method of treating papillomavirus (see claim 15). The above cited art taught deletion of C-terminal region, which would mean the N-terminus

Art Unit: 1648

is maintained and would render the positive response envisioned by the Applicants' own product, and method. As applicants have pointed out in the specification the antigenic regions are resided in the N-terminus region of HPV-18 and Gissmann et al also maintains the same regions in their composition (see claims 1, 2, 4). The product disclosed in the above cited patent appears to be identical or so similar that is indistinguishable from the product claimed by the applicants.

Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claims 1-4, 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Gissmann et al (WO 96/11272)

The disclosure of the above cited art meets the broad limitations of the claims. The above cited patent taught various chimeric virus like particles as now claimed (see page 16, lines 21-31).

Claims 1-2, 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Lowy et al (US Patent no. 5,618,536).

The teaching and the claims of the above cited patent meets the broad limitations of the claimed invention. The above cited art taught various chimeric virus like particles as now claimed (see claims 1, 2-4). In addition, the above art also taught a method of treating papillomavirus (see claim 15).

Art Unit: 1648

No claims are allowed.

***Conclusion***

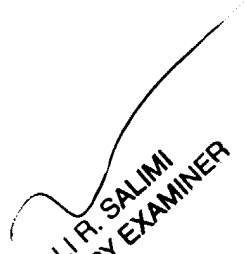
Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

A. R. Salimi

5/27/2004

  
ALI R. SALIMI  
PRIMARY EXAMINER